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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/824,341

04/14/2004

Gary W. Guenst

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EXAMINER

TYSON, MELANIE RUANO

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/824,341	<b>Applicant(s)</b> GUENST, GARY W.	
	<b>Examiner</b> Melanie Tyson	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 32-42 is/are pending in the application.
- 4a) Of the above claim(s) 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 16-20, and 32-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This action is in response to the applicant's amendment received on 09 February 2009. Claims 21-31 remain cancelled. Claim 15 remains withdrawn from consideration.

#### ***Response to Arguments***

Applicant's arguments filed 09 February 2009, with respect to the rejection of the claims under 35 USC § 103 have been fully considered and are persuasive. Therefore, the FINAL rejection has been withdrawn. However, upon further consideration, a new FINAL ground of rejection is made in view of Duhaylongsod et al. and Blum (see rejection below).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 1-3, 5-14, 16, 17, 32-34, 36-42** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Duhaylongsod et al. (U.S. Patent No. 6,241,741 B1)** and **Blum (U.S. Patent No. 4,230,119)**.

Duhaylongsod discloses a method of joining a blood conduit to a blood vessel (see entire document) comprising the steps of making an incision (18) in the blood vessel wall (14), inserting a tubular member (80) into a conduit (26,12), advancing the tubular member through the incision located on a proximal end thereof (for example, see Figure 7), fixedly joining the conduit to the vessel wall (balloon, or weakened wall region 82, is inflated via an oxygen flow and expanded radially outward, expanding the end portion of the conduit to engage the wall and also discloses may utilize biological glue), and after fixedly joining the conduit to the vessel withdrawing the tubular member through the conduit (for example, see column 7, lines 17-48). The oxygen flows through the tubular member, which is positioned within the blood vessel, thus it is considered to flow into the blood vessel as claimed. Duhaylongsod fails to disclose the flow is an oxygenated liquid.

Blum discloses a method of joining a conduit to a vessel (see entire document). Blum teaches providing an oxygenated liquid flow (sterile saline solution) via a bulb (13) through the tubular member to expand its weakened distal regions (for example, see Figure 2 and column 3, line 37). Expanding tubular members with an oxygen flow was known in the art, as evidenced by Duhaylongsod, while expanding tubular members with an oxygenated liquid flow was known in the art as evidenced by Blum. One of ordinary skill in the art could have substituted Duhaylongsod's oxygen flow and the

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results would have been a predictable use of expanding a tubular member. Thus, it would have been obvious to one of ordinary skill in the art to substitute Duhaylongsod's oxygen flow with an oxygenated liquid flow.

With respect to claims 2 and 33, Duhaylongsod discloses inserting a tubular member into a conduit and advancing a tubular member through a vessel (see rejection above), wherein the inserting is performed after the advancing. The applicant has not disclosed that performing the inserting before advancing provides an advantage, is used for a particular purpose, or solves a stated problem over inserting after advancing. Furthermore, the applicant discloses that the inserting may be performed either before or after advancing. It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the inserting before the advancing, since the reversal of these steps involves only routine skill in the art.

With respect to claims 5, 6, 36, and 37, Duhaylongsod discloses the blood vessel may be a coronary artery. The applicant has not disclose that utilizing a saphenous vein or internal mammary artery as the conduit provides an advantage, is used for a particular purpose, or solves a stated problem over utilizing other veins, arteries, and synthetic vascular grafts. Furthermore, both the applicant and Duhaylongsod disclose that in addition to a thoracic artery, other vessels, arteries, or synthetic vascular grafts may be used. Therefore, it would have been obvious to modify the conduit of Duhaylongsod to obtain the invention as specified in claims 5, 6, 36, and 37.

With respect to claims 9-12, 40, and 41, the applicant has not disclosed that utilizing blood supplied from the femoral artery or aorta provides an advantage, is used

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for a particular purpose, or solves a stated problem over utilizing other oxygenated fluids. Furthermore, the applicant discloses that any suitable oxygenated fluid may be utilized and it appears the oxygenated liquid disclosed by Blum would perform equally well.

With further respect to claims 14 and 42, Duhaylongsod's (in view of Blum) oxygenated fluid is provided at a certain pressure in order to expand the tubular member. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the pressure higher than that of the patient's blood pressure, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

With further respect to claim 17, it has been held that to be entitled to weight in method claims, the recited structure limitations (port that is distinct from the proximal end) therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961).

With further respect to claim 32, Duhaylongsod's graft connection position has been considered to be "near the blood vessel proximal end" of the blood vessel. In the alternative, it would have been obvious to one having ordinary skill in the art at the time the invention was made to position the graft connection to or near the blood vessel proximal end, since the applicant has not disclosed that positioning the graft connection at or near the blood vessel proximal end provides an advantage is used for

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a particular purpose, or solves a stated problem and it appears the invention would perform equally well at the position disclosed by Duhaylongsod.

**Claims 4 and 35** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Duhaylongsod et al.** and **Blum** as applied to claims 1 and 32 above, and further in view of **Stanish (U.S. Patent No. 6,585,762 B1)**. Duhaylongsod and Blum disclose the claimed invention except that the step of fixedly joining includes suturing the conduit to the blood vessel. Stanish discloses a method of joining a blood conduit to a blood vessel wall (see entire document). Stanish teaches suturing the conduit to the blood vessel wall in order to advantageously secure the conduit to the vessel (for example, see column 7, lines 37-41). Duhaylongsod discloses the conduit may be further secured to the blood vessel using an adhesive suggesting that an enhanced security may be desired in some cases. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to suture the conduit to the blood vessel in the method of Duhaylongsod and Blum. Doing so would enhance the security between the conduit and vessel.

**Claims 18-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Duhaylongsod et al.** and **Blum** as applied to claim 1 above, and further in view of **Amor et al. (U.S. Patent No. 6,059,809)**. Duhaylongsod and disclose the claimed invention except for the step of inserting a stiffening member within the tubular member. Amor discloses a method (see entire document) comprising the steps of inserting a

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tubular member (4) through a conduit (8) and into a vessel. Amor teaches inserting a stiffening member (6) within the tubular member (4) in order to serve as a guide through the vessel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to insert a stiffening member within Duhaylongsod's (in view of Blum) tubular member. Doing so would provide a means for guiding the tubular member through the vessel, thus preventing inadvertent damage to the blood vessel wall.

### ***Conclusion***

Applicant's amendment dated **02 July 2007** necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-



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9062. The examiner can normally be reached on Monday through Friday 7-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./  
Examiner, Art Unit 3773  
March 1, 2009

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3773